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WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO CA 94304-1050

AUG 25 2006

In re Application of :
Elizabeth Moyer et al :
Serial No.: 09/393,590 : PETITION DECISION
Filed: September 9, 1999 :
Attorney Docket No.: 31242.701.201 :
:

This is in response to the petition under 37 CFR 1.181, filed June 6, 2006, requesting withdrawal of the Finality of the last Office action. This decision takes the place of a decision improperly mailed to applicants on August 21, 2006, which decision is hereby vacated.

BACKGROUND

A review of the recent file history of this application shows that following the filing of RCE papers on February 23, 2004, the examiner mailed to applicants a non-Final Office action on June 1, 2004. Applicants replied on December 1, 2004, and an interview with the examiner was held on April 1, 2005.

The examiner mailed another non-Final Office action to applicants on July 21, 2005. The Office action included a discussion of affidavits filed for the purpose of overcoming certain rejections and those rejections were indicated as withdrawn. The examiner then rejected claims 1-8 and 16-21 under 35 U.S.C. 102(b) as anticipated by Schwarz (of record). Claims 1-8 and 16-21 were also rejected under 35 U.S.C. 102(b) as anticipated by Saprykina et al (of record). Claims 1-8 and 16-21 were further rejected under 35 U.S.C. 102(b) as anticipated by Sacks et al (of record). Claims 1-8, 12-21 and 25-25 were rejected under 35 U.S.C. 102(b) as anticipated by Schantz et al (of record). Claims 14-15 and 27-28 were rejected under 35 U.S.C. 103(a) as unpatentable over Schwarz or Saprykina et al or Sacks et al in view of Schantz et al. Claims 9-11 and 22-24 were also rejected under 35 U.S.C. 103(a) as unpatentable over Schwarz or Saprykina et al in view of Melling et al. Lastly, claims 12-13 and 25-26 were found unpatentable under 35 U.S.C. 103(a) over Sacks et al. Each of the rejections was clearly and concisely explained.

Applicants replied on September 13, 2005, amending claims 1, 4, 6-7, 16, 18-20, 29 and 40-41 (claims 29-53 are withdrawn from consideration). The amendments served to generally clarify the claim scope and place the claims in better condition for examination.

The examiner mailed a Final Office action to applicants on December 8, 2005, referencing the interview of 9/30/05 (sic 9/07/05) and discussing claim interpretation as to certain terms. The

examiner then withdrew specifically every rejection made in the previous Office action indicating, however, for certain rejections that they were being restated in modified form. The examiner then rejected claims 1 and 16 under 35 U.S.C. 112, first paragraph, for containing subject matter not described in the specification (lack of written description) for such terms as "stabilized" liquid or "capable of being" stable or "buffered saline" or certain pH ranges, etc. Claims 6 and 19 were rejected under 35 U.S.C. 112, first paragraph, for including new matter. Claims 7 and 20 were rejected under 35 U.S.C. 112, first paragraph, for new matter. Claims 1-14 and 16-27 were rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. Claims 1-28 were then rejected under 35 U.S.C. 112, second paragraph, as indefinite with specific terms identified as indefinite. Claims 1-3, 5-8, 16-17 and 19-21 were rejected under 35 U.S.C. 102(b) as anticipated by Sacks et al (of record). Claims 1-8, 12-21 and 25-28 were rejected under 35 U.S.C. 102(b) as anticipated by Schantz et al (of record). Lastly, claims 1-9, 11 16-22 and 24 were rejected under 35 U.S.C. 103(a) as unpatentable over Schwarz in view of Schantz et al. Each rejection was properly and carefully explained. The art rejections applied are similar in nature to those previously applied, but have some substantial differences included. The examiner made the action Final stating that the new grounds of rejection were necessitated by applicants' amendments to the claims.

Applicants filed an amendment after Final rejection on May 5, 2006, requesting that the examiner withdraw the Finality of the previous Office action and presenting substantial amendments to the claims in response to the rejections set forth in the Office action. Concurrently applicants filed a Notice of Appeal.

The examiner mailed an Advisory Action to applicants on May 12, 2006, denying entry of the amendment as raising new issues requiring further search, new matter and not placing the application in better condition for appeal. The examiner explained the reasons for non-entry.

Applicants then engaged the examiner in telephonic interviews seeking to hold a personal interview with the examiner. Based on applicants' proposed points of discussion as not likely leading to progress or disposition of the application, the request for a personal interview was denied with reasons set forth by the examiner.

This petition was then filed on June 6, 2006, requesting Supervisory review of the Final Office action or alternately as a petition to review the finality of the rejection. As a petition is considered a Supervisory review, this request is being treated as a petition.

DISCUSSION

Initially it is noted that this application has been pending for nearly six years and has received at least five substantive Office actions (including one previous Final Office action) following an initial restriction requirement and it is desirable to bring the prosecution to a close as speedily as possible. It is presumed that the examiner made the last Office action Final for that purpose.

However, a review of the last two Office actions shows that they are markedly different. As noted above the examiner set forth numerous rejections over prior art in the Office action mailed July 21, 2005, and then specifically withdrew each of those rejections in the next Office action

and presented new prior art rejections. The examiner stated that the new rejections were in consequence of applicants' amendments to the claims. However a review of those amendments fails to show that they were of significant substance so as to cause new rejections over prior art to be made. A summary of some the changes is as follows:

"stable liquid" changed to "stabilized liquid;
"providing a buffered pH range to the formulation between" (underlined part added);
"a therapeutic concentration suitable for use in humans of purified botulinum toxin";
"and [wherein said] the formulation is capable of being stable as a liquid when stored for at least a year" (deleted matted in brackets); and
"buffered saline [buffer]".

As can be seen these amendments do not materially affect the scope of the claims, but generally amend terms in dependent claims to agree with independent claims, narrow or clarify specific claim limitations or express implied limitations.

Rather the examiner in reporting the substance of the interview in the Office action devotes most of a page to explaining claim interpretation to applicants, focusing on such terms as "buffered saline" as opposed to "saline buffer", for instance, and how the Office interpretation of claim terms may differ from that of the courts. The examiner then sets forth rejections under 35 U.S.C. 112, first paragraph, of these and other terms designating them as new matter and/or lacking written description or enablement in the specification. Clearly these rejections were not necessitated by applicants' amendments, but should have been raised in a previous Office action so that applicants could properly respond to them.

The examiner then restates three rejections of record in light of the claim interpretations set forth. The rejection under 35 U.S.C. 102(b) over Sacks et al is significantly different from the previous rejection over Sacks et al. Portions of the rejections are directed to claim interpretation, as noted above, but other parts are significantly different arguments not previously presented. The rejection under 35 U.S.C. 103(a) is also different in that only Schwarz and Schantz et al are used rather than the previous combinations.

In view of the significant change in the prior art rejections as well as the new rejections under 35 U.S.C. 112, first paragraph, which were not necessitated by applicants' amendments the making of the Office action mailed December 8, 2005, was improper and the finality thereof is hereby withdrawn.

DECISION

The petition is **GRANTED**.

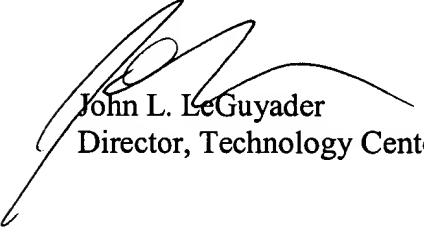
The application will be forwarded to the examiner for entry and further consideration of the amendment filed May 5, 2006, in response to the Office action of December 8, 2005, which is now considered to be a non-Final Office action. As a consequence of withdrawal of finality of the last Office action the Notice of Appeal is considered premature and is withdrawn. Applicants are not under obligation to file an Appeal Brief. Applicants may

reinstate the Notice of Appeal in response to any subsequent Final Office Action or may request refund of the Appeal Fee.

OTHER MATTERS

Applicants' comments on requests for an interview and denial thereof by the examiner are noted, but have no effect on this decision. Whether an examiner grants an interview to applicants after a Final Office action is discretionary with the examiner. In this particular instance it is noted that applicants have had at least two previous personal interviews with the examiner and some progress towards disposition of this application is presumed to have occurred. Here, the examiner indicated that progress towards disposition of the application would not likely occur and declined an interview. Such is within the examiner's prerogative.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number 571-273-8300.



John L. LeGuyader
Director, Technology Center 1600